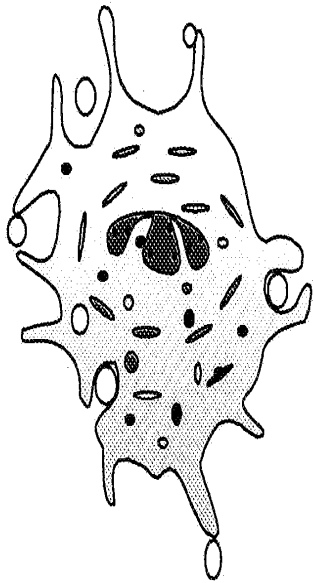


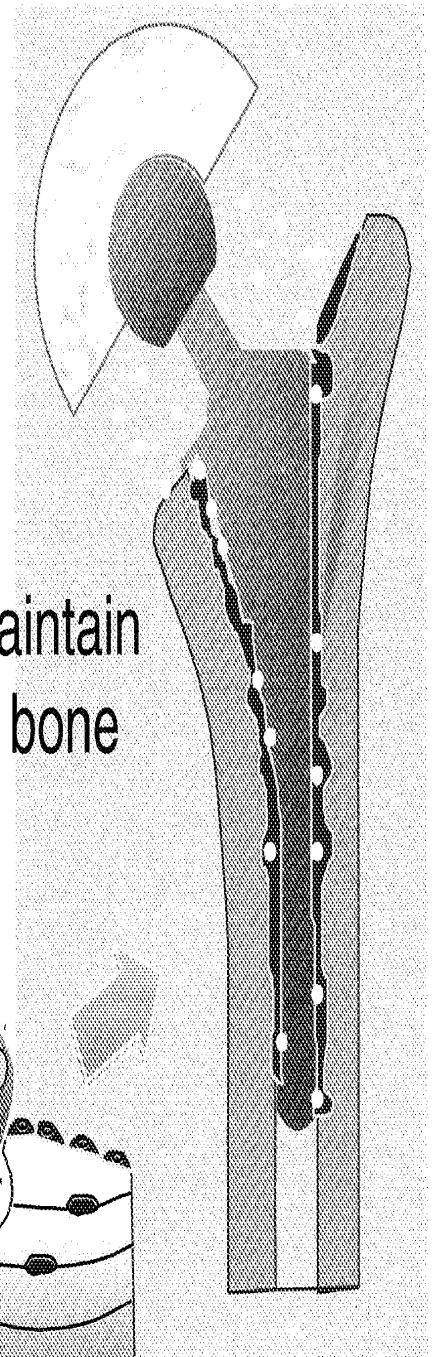
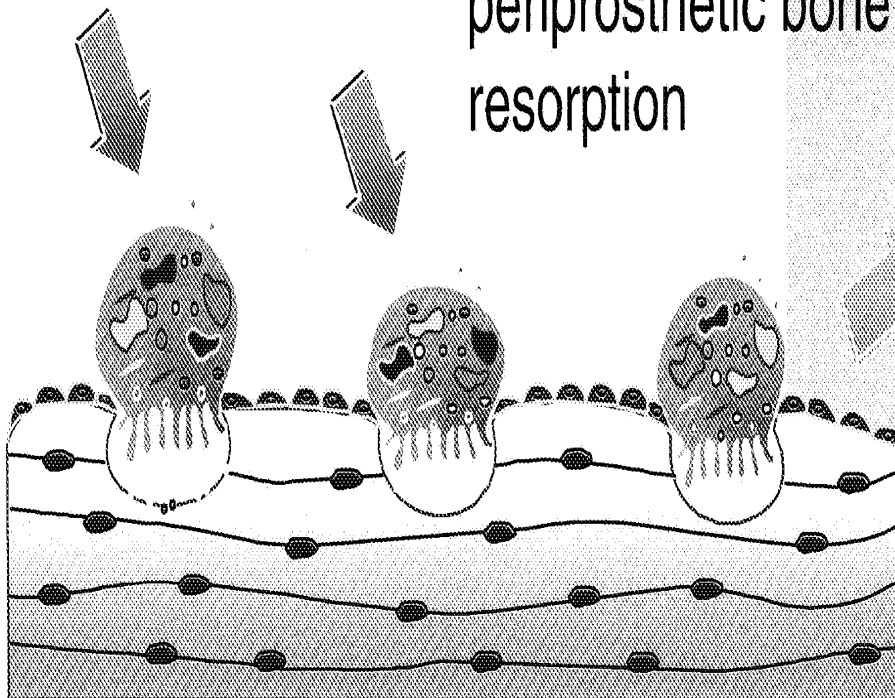
# Problem 1: Wear

## Particle Disease – Osteolysis

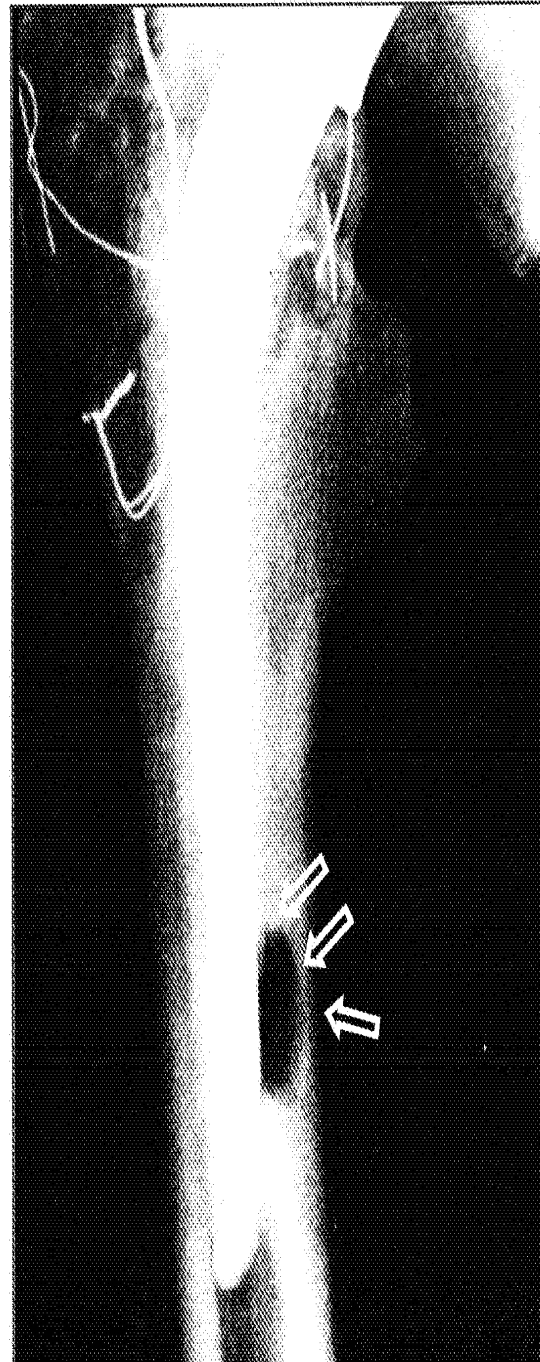
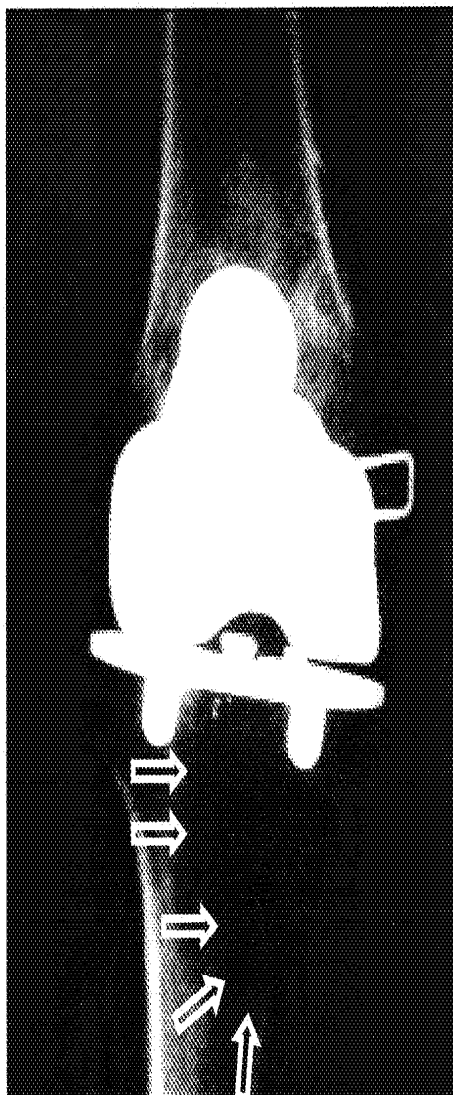


Various cytokines  
Collagenase,  
Gelatinase

Initiate and maintain  
periprosthetic bone  
resorption

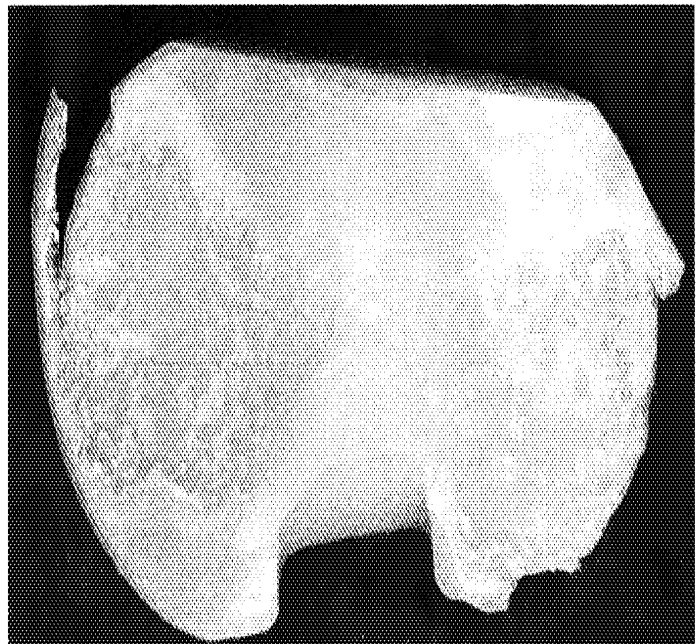


# Radiological manifestation of osteolysis

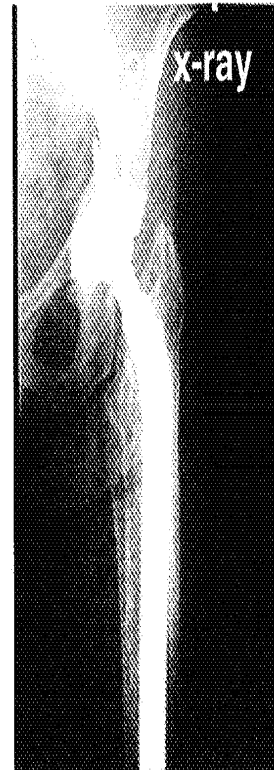
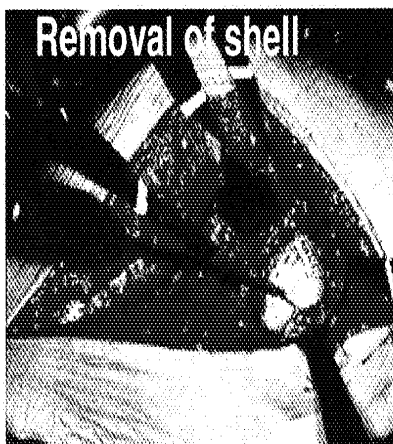
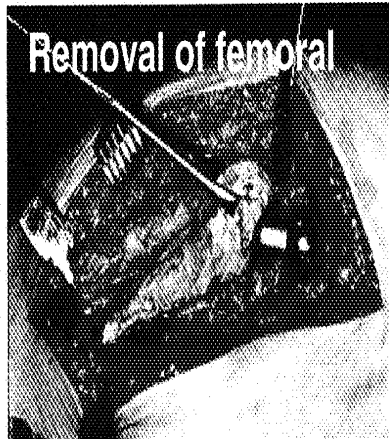
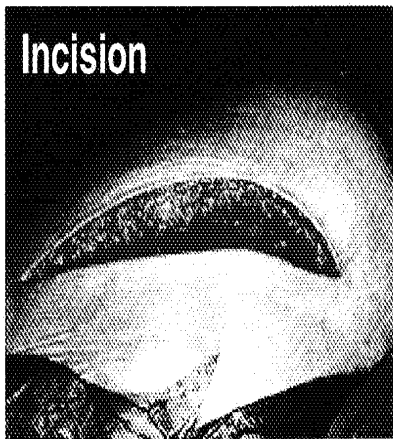


## Problem 2: Oxidation Induced Damage

- Terminal gamma sterilization
- Induces residual free radicals
- Which over time causes oxidation of the polymer in vivo



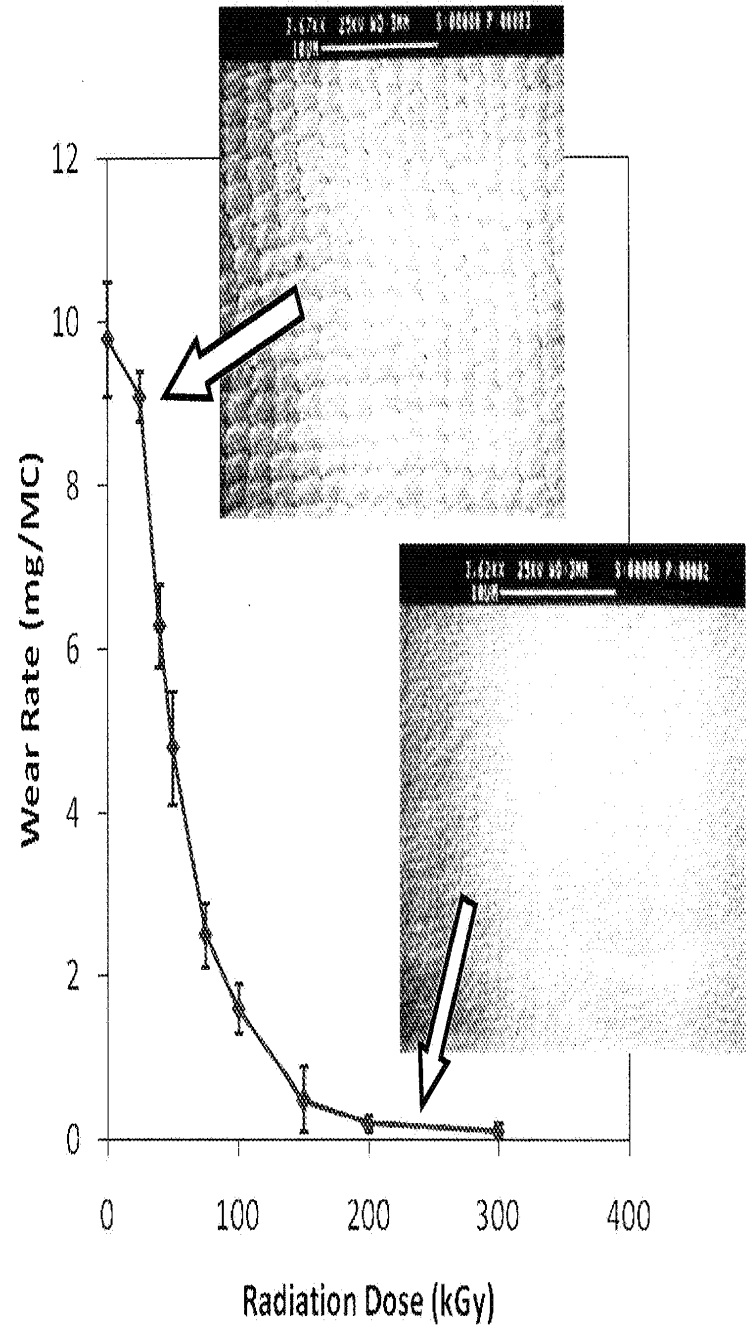
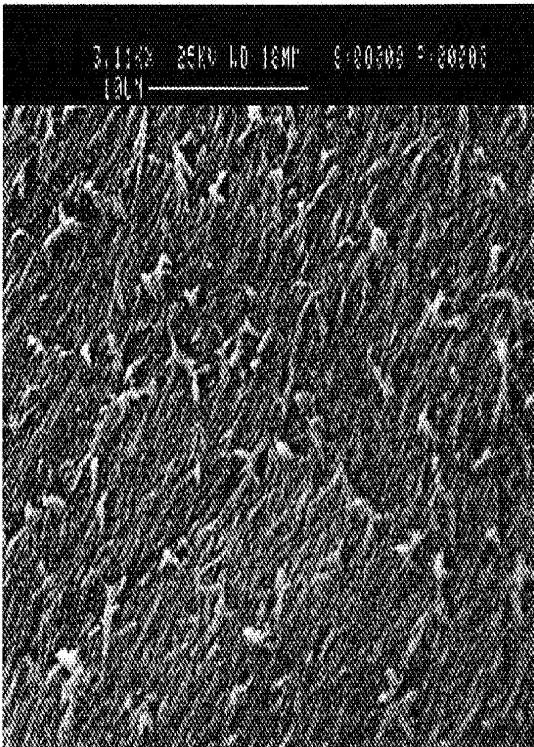
# Typical revision hip surgery



**Revision Surgeries are typically  
caused by WEAR and OXIDATION**

**AIMS**  
**Improve wear**  
**Improve oxidation**

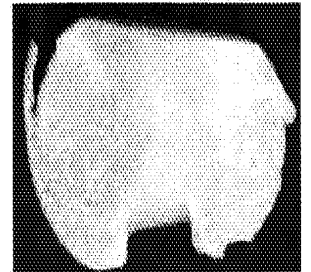
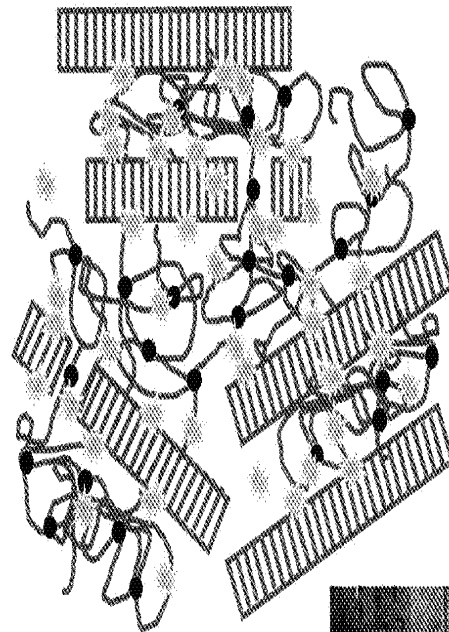
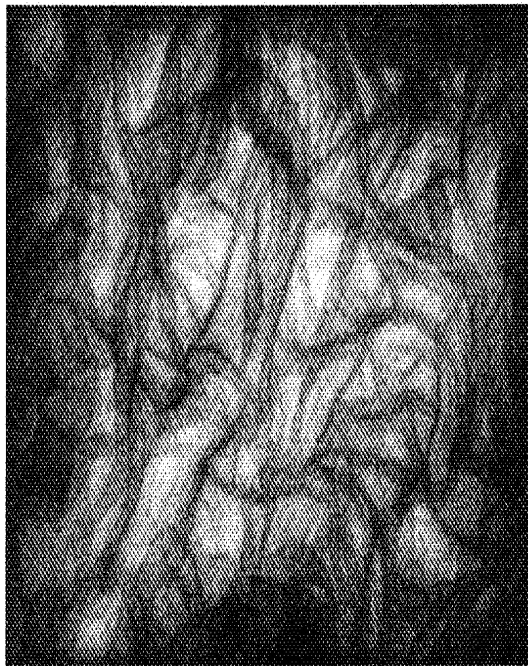
# Solution to Wear: Crosslinking



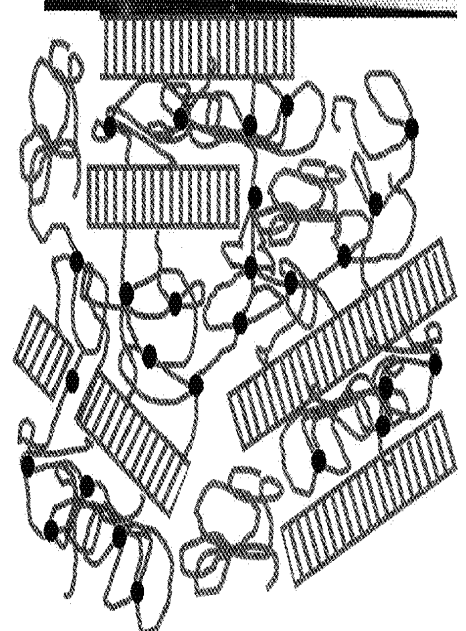
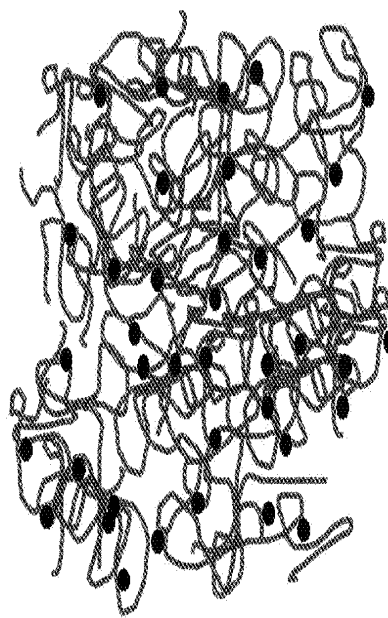
Muratoglu et al., Biomaterials, 20:1463, 1999



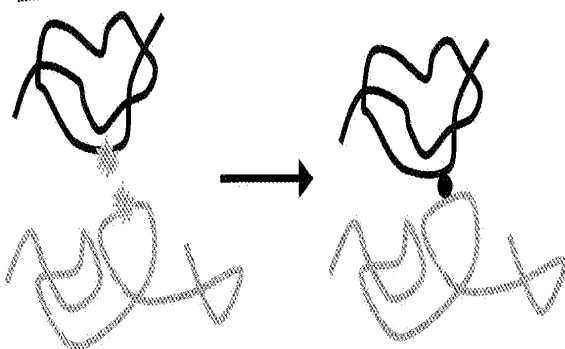
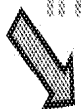
# Problem: Radiation Induces Oxidation



Melting



Irradiation



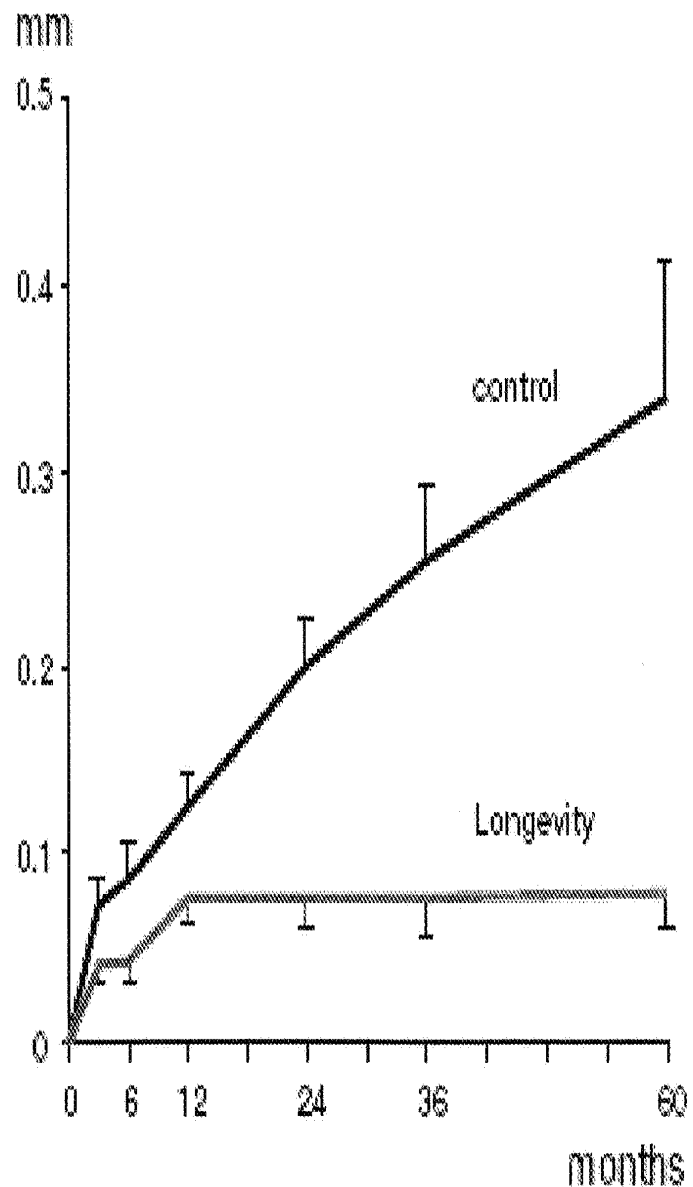
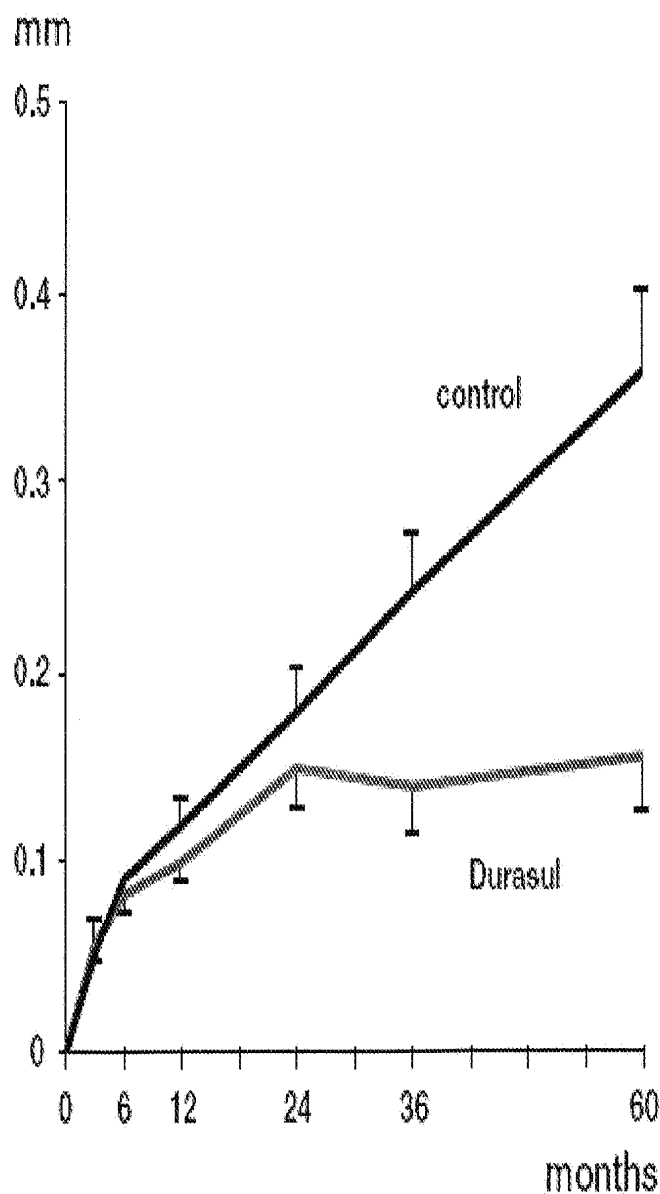


# 5-year experience of highly cross-linked polyethylene in cemented and uncemented sockets

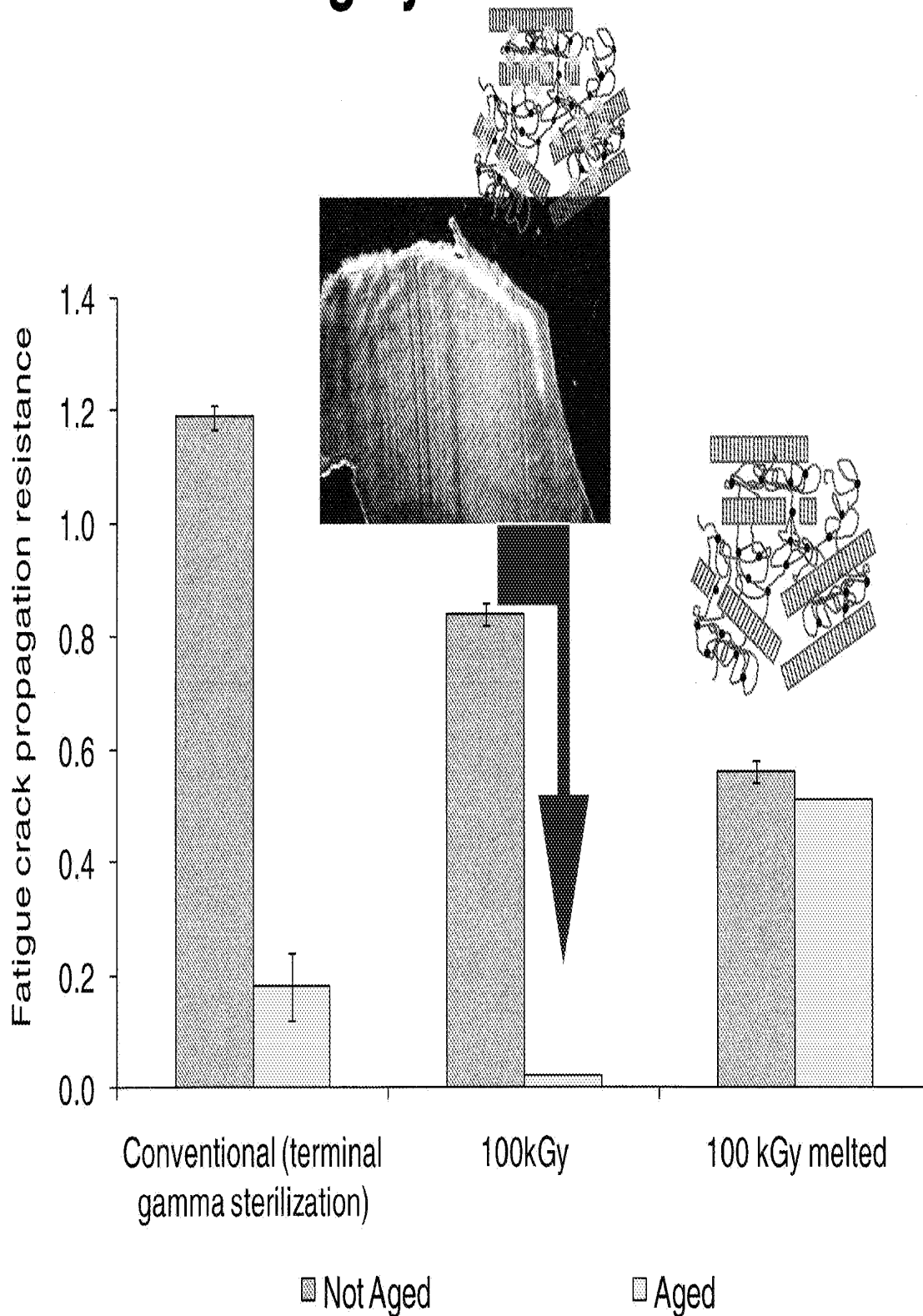
Two randomized studies using radiostereometric analysis

Acta Ortho. (2007)

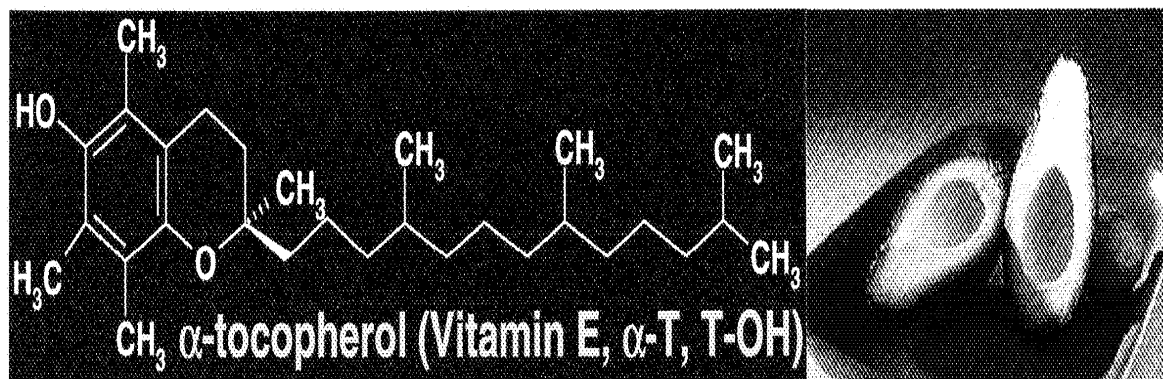
Georgios Digas, Johan Kärrholm, Jonas Thanner, and Peter Herberts



# 1<sup>st</sup> Generation Highly Crosslinked UHMWPEs



## Use of an antioxidant to stabilize free radicals: Vitamin-E



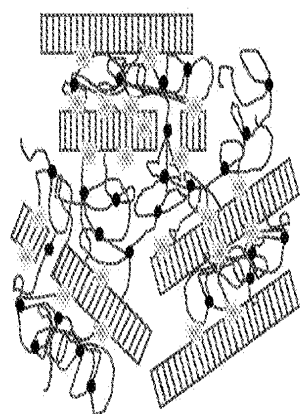
Chain reaction cycle leads to oxidation and failure



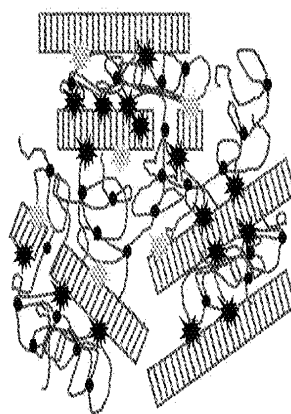
But with Vitamin-E



Chain reaction cycle is broken by vitamin-E

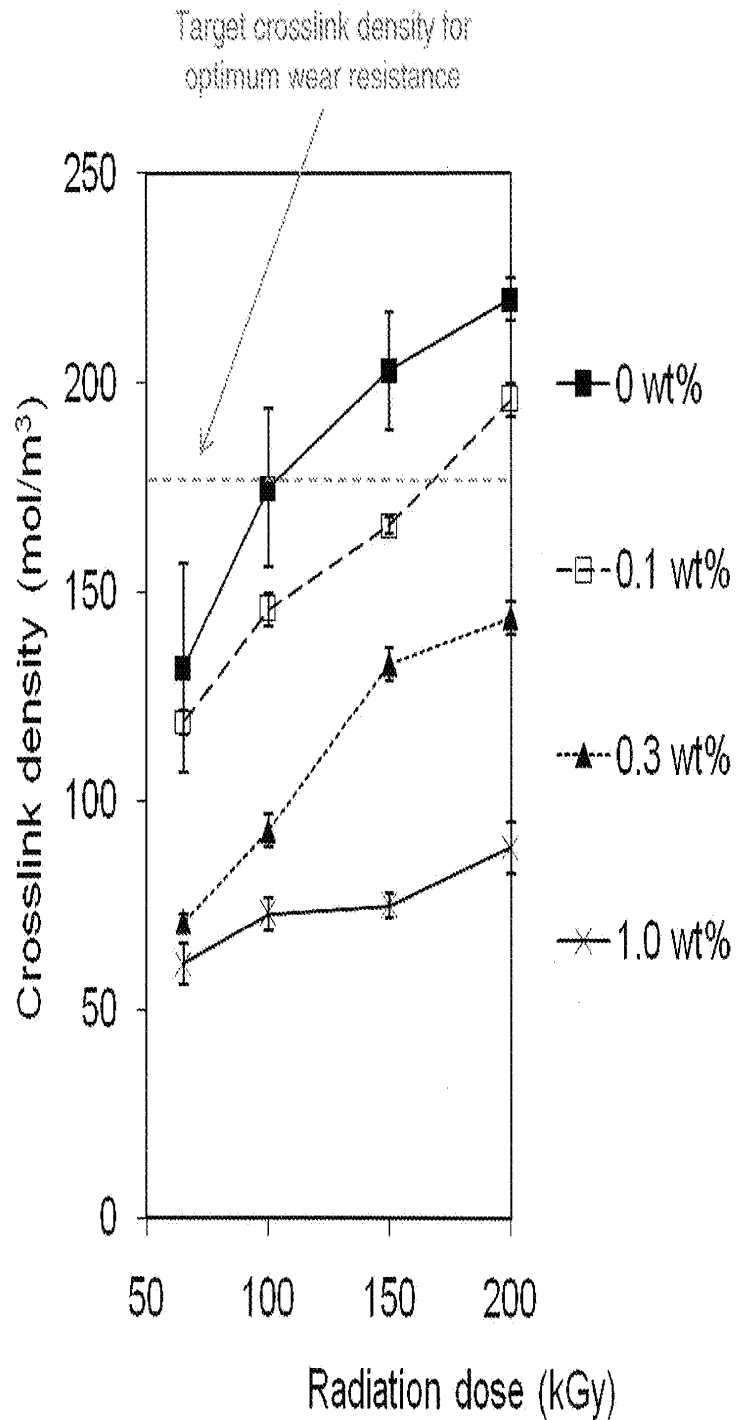
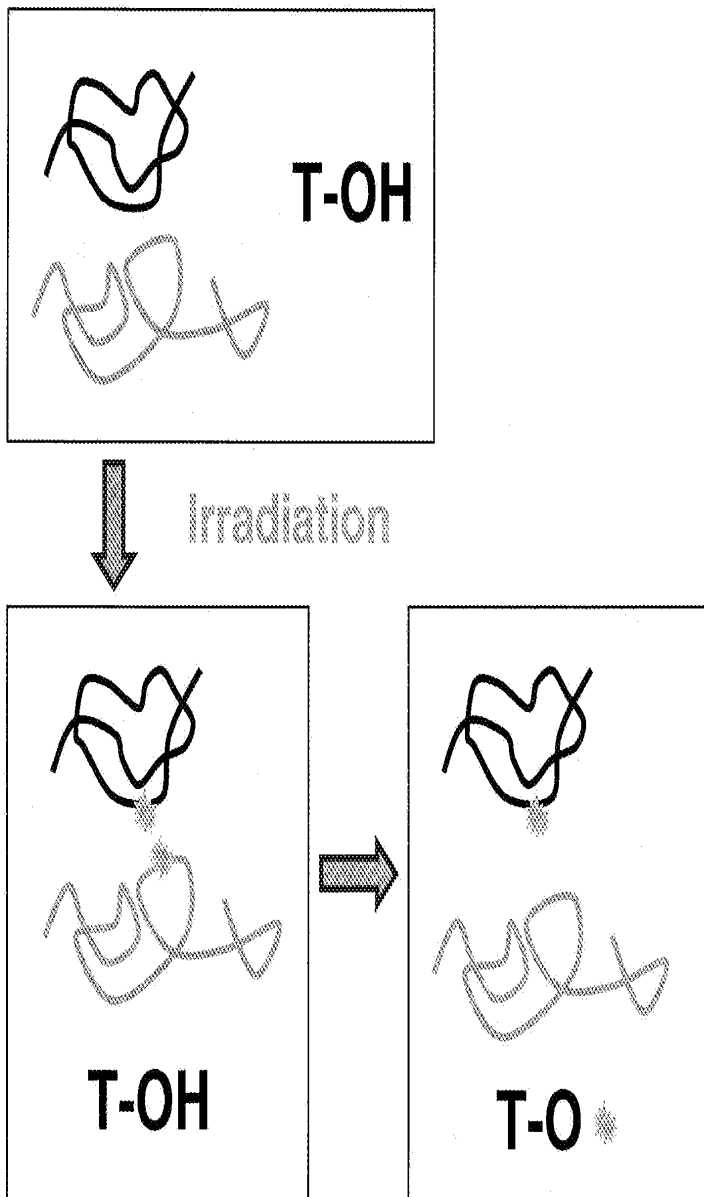


+ Vitamin-E

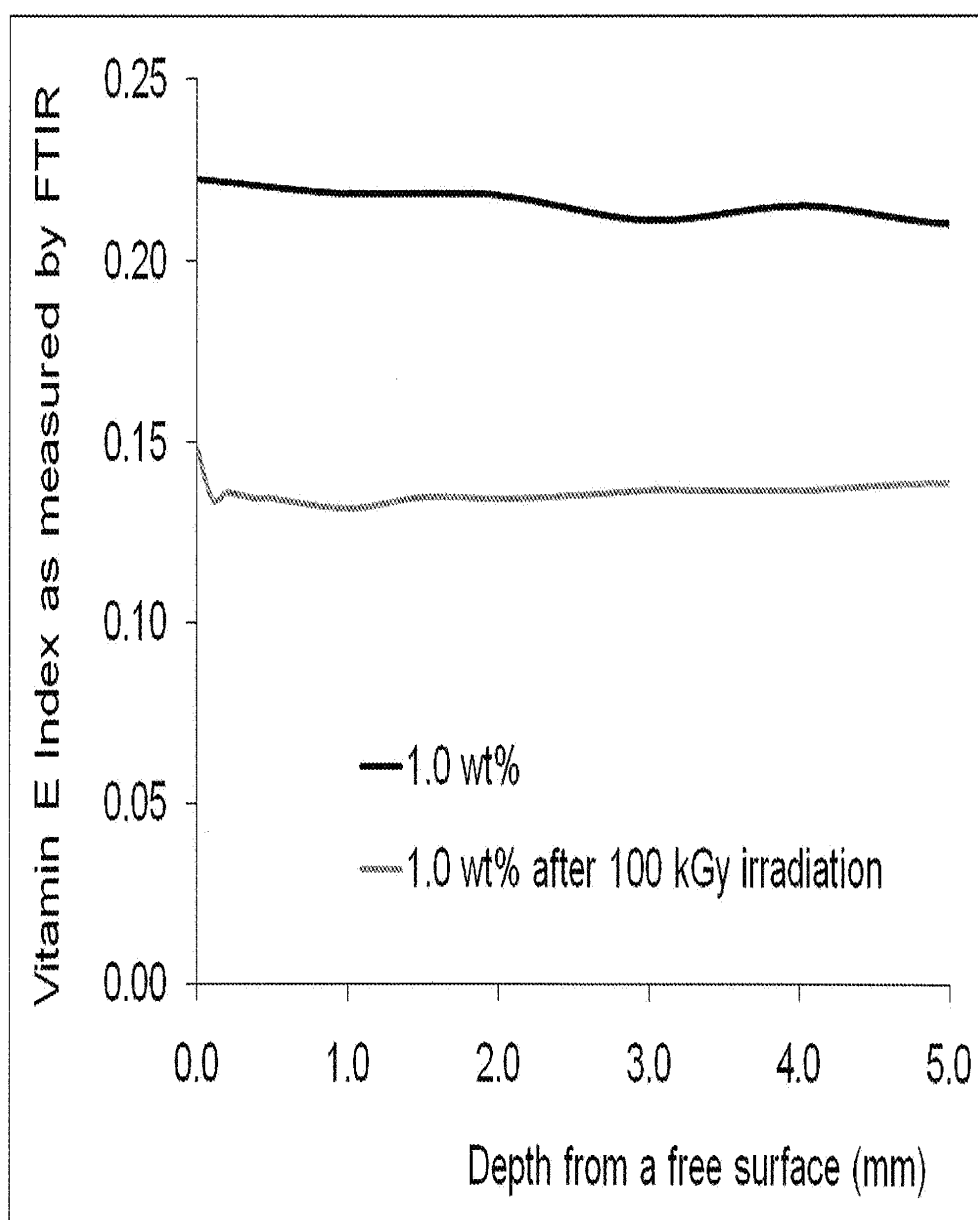


# HOWEVER!

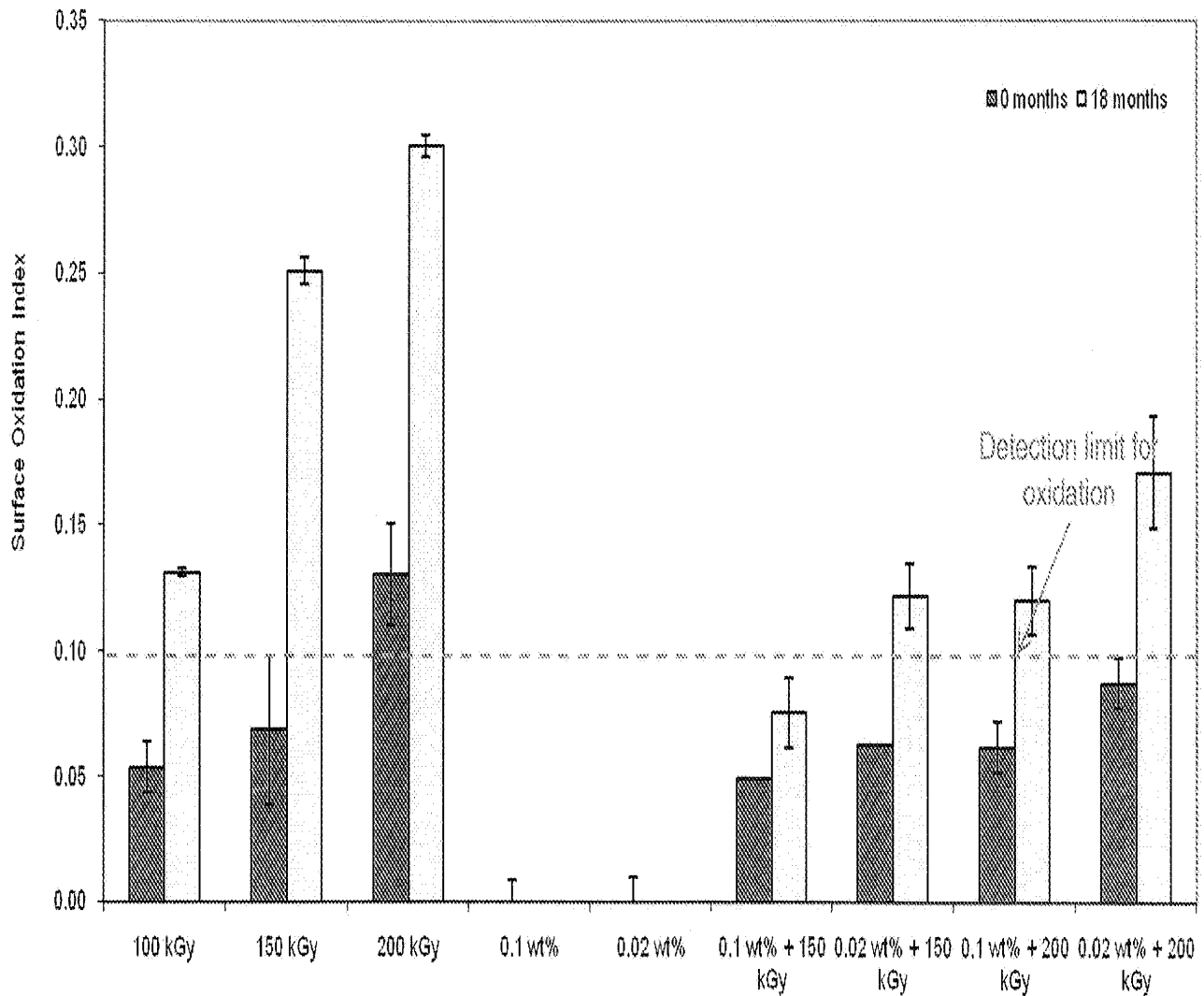
- Vitamin-E inhibits crosslinking by radiation



Vitamin E is a free radical scavenger, therefore it reacts with the free radicals on the polyethylene chains in its vicinity. These reactions during radiation deplete some of the vitamin E, which is then not available for preventing polyethylene against oxidation after irradiation.

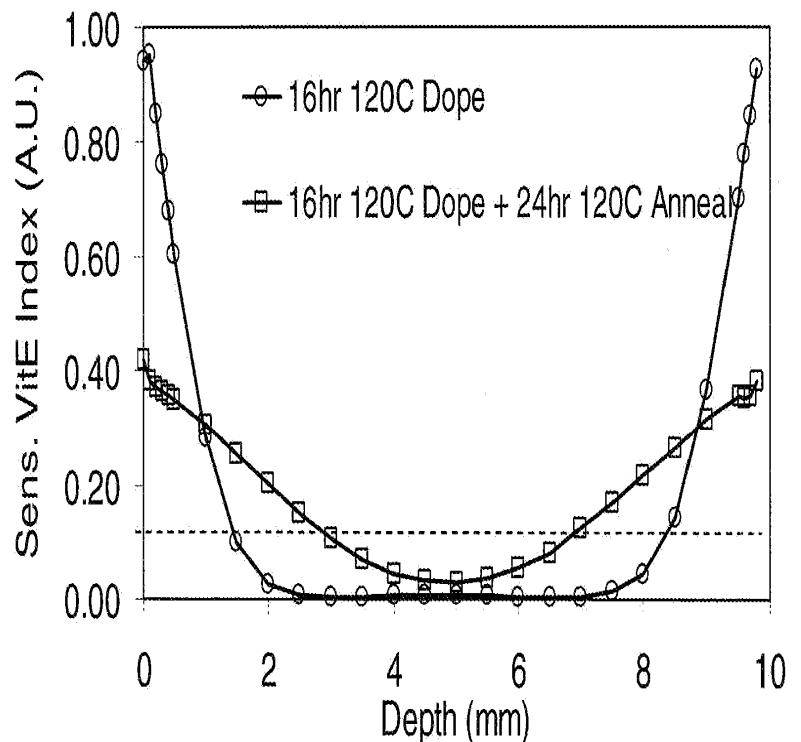
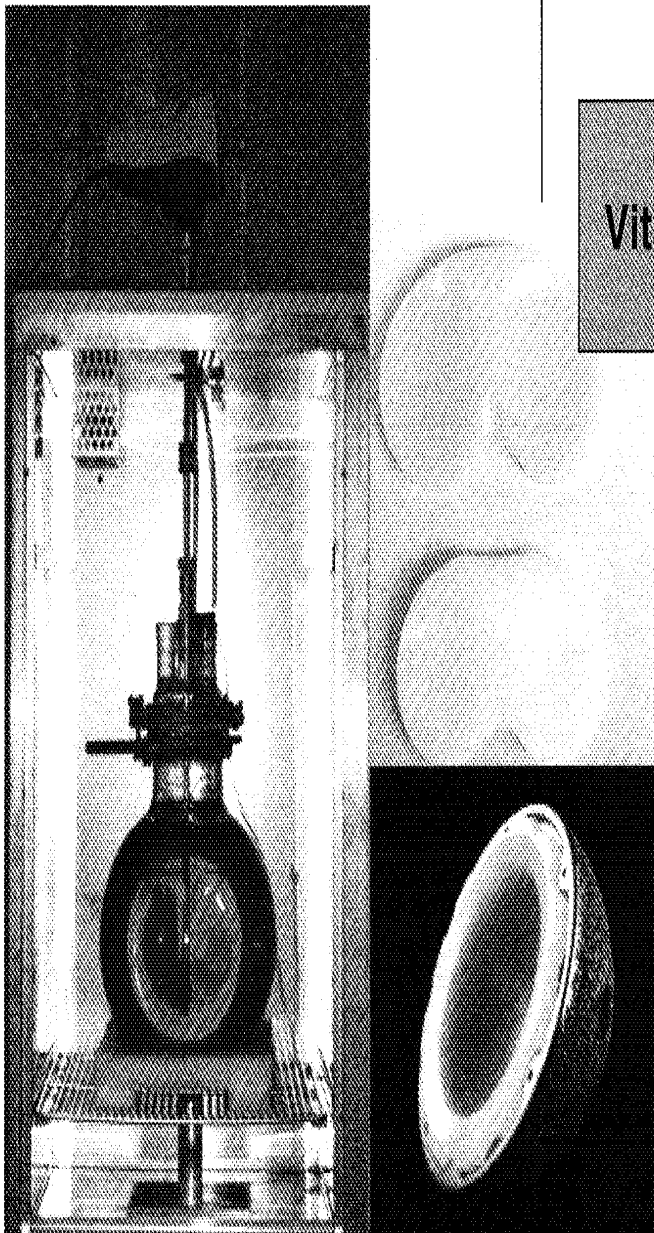
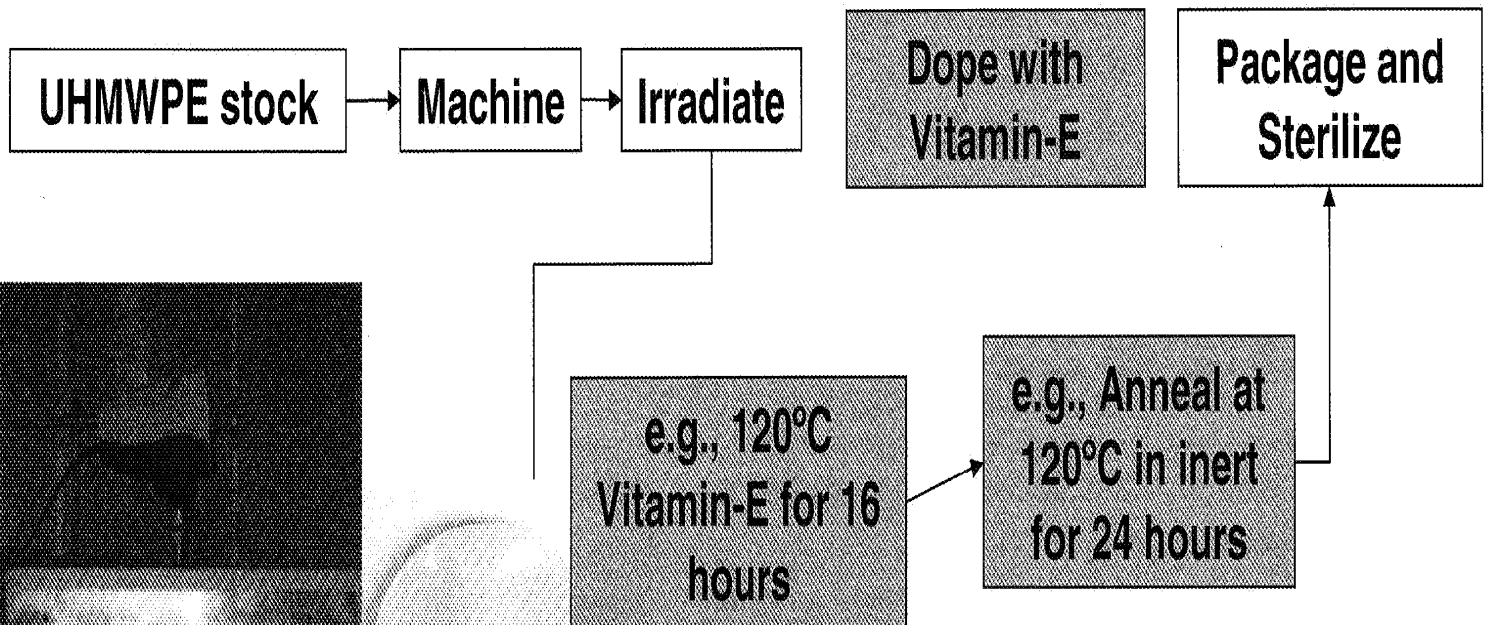


# Oxidation resistance



Radiation crosslinked only	Blends with no crosslinking	Room Temperature Radiation Crosslinked Blends
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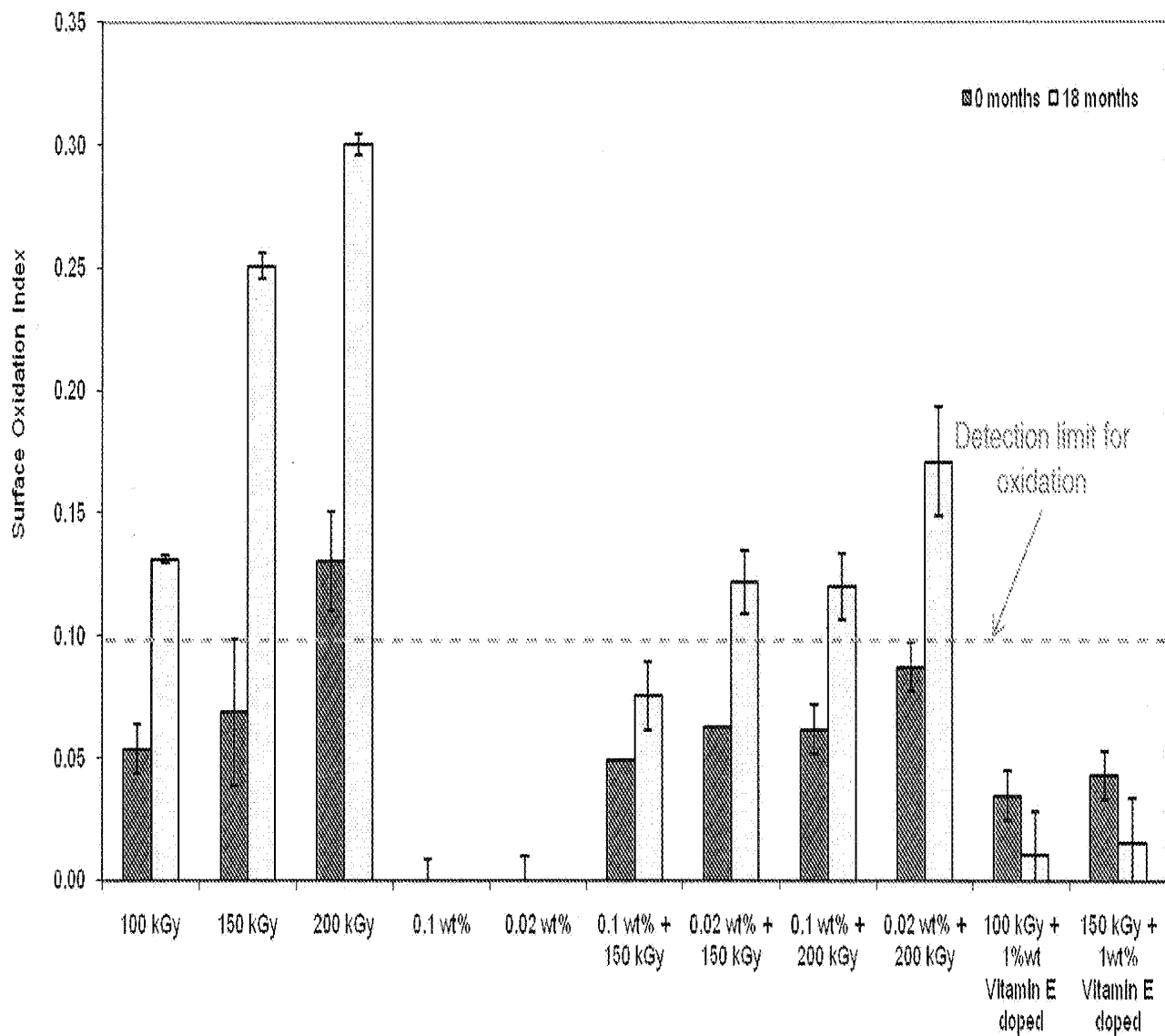
# Solution: Antioxidant Doping after Irradiation





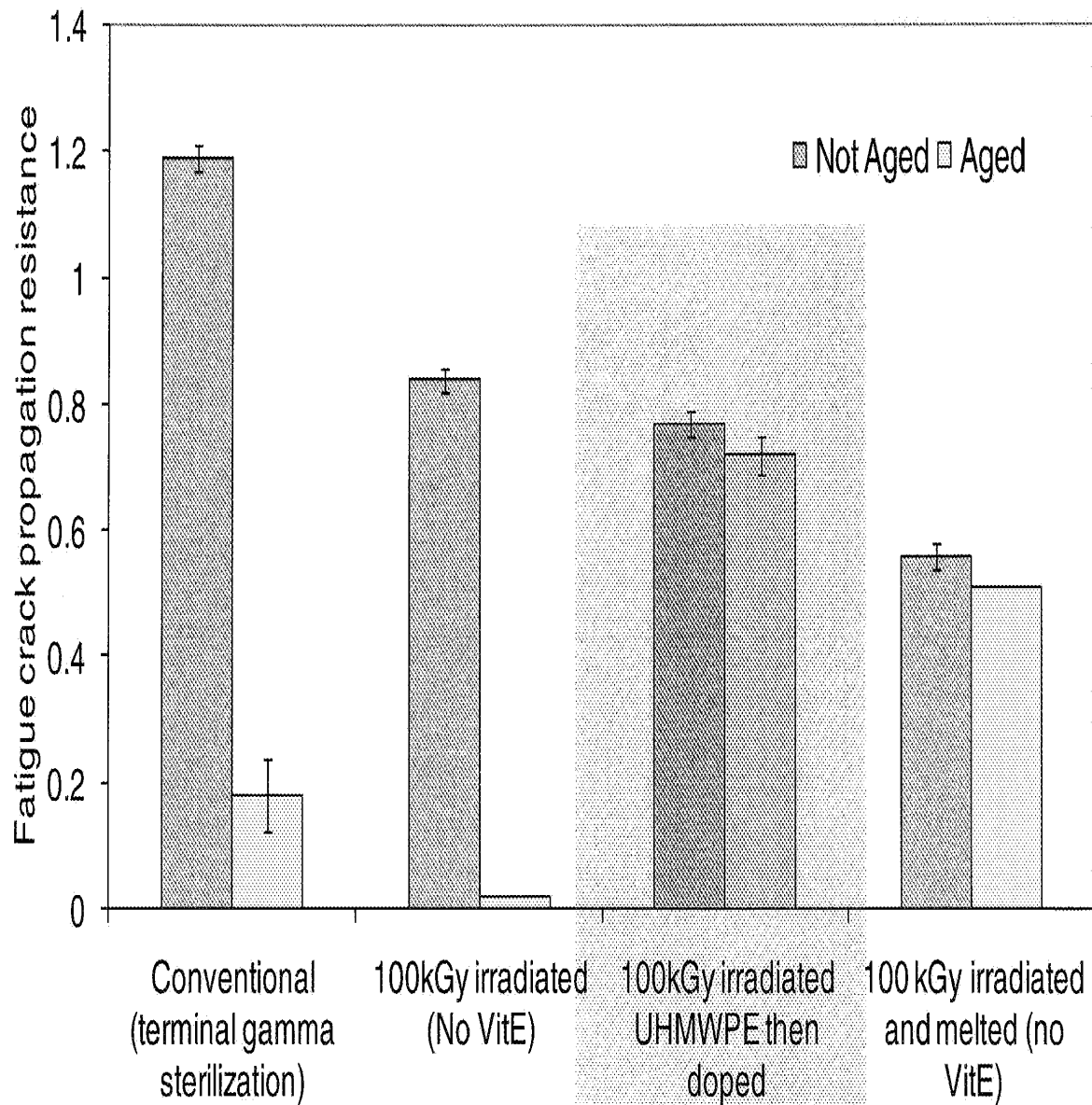
# Oxidation resistance: RT

## Irradiated Blends vs. Irradiated and Doped



Radiation crosslinked only	Blends with no crosslinking	Room Temperature Radiation Crosslinked Blends	Radiation Crosslinked and doped
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# Fatigue Crack Propagation Resistance



Oral et al. Journal of Arthroplasty 21(4): 580-591 (2006)

Oral et al. Biomaterials 25: 5515-5522 (2004)

## Importance of preserving fatigue strength

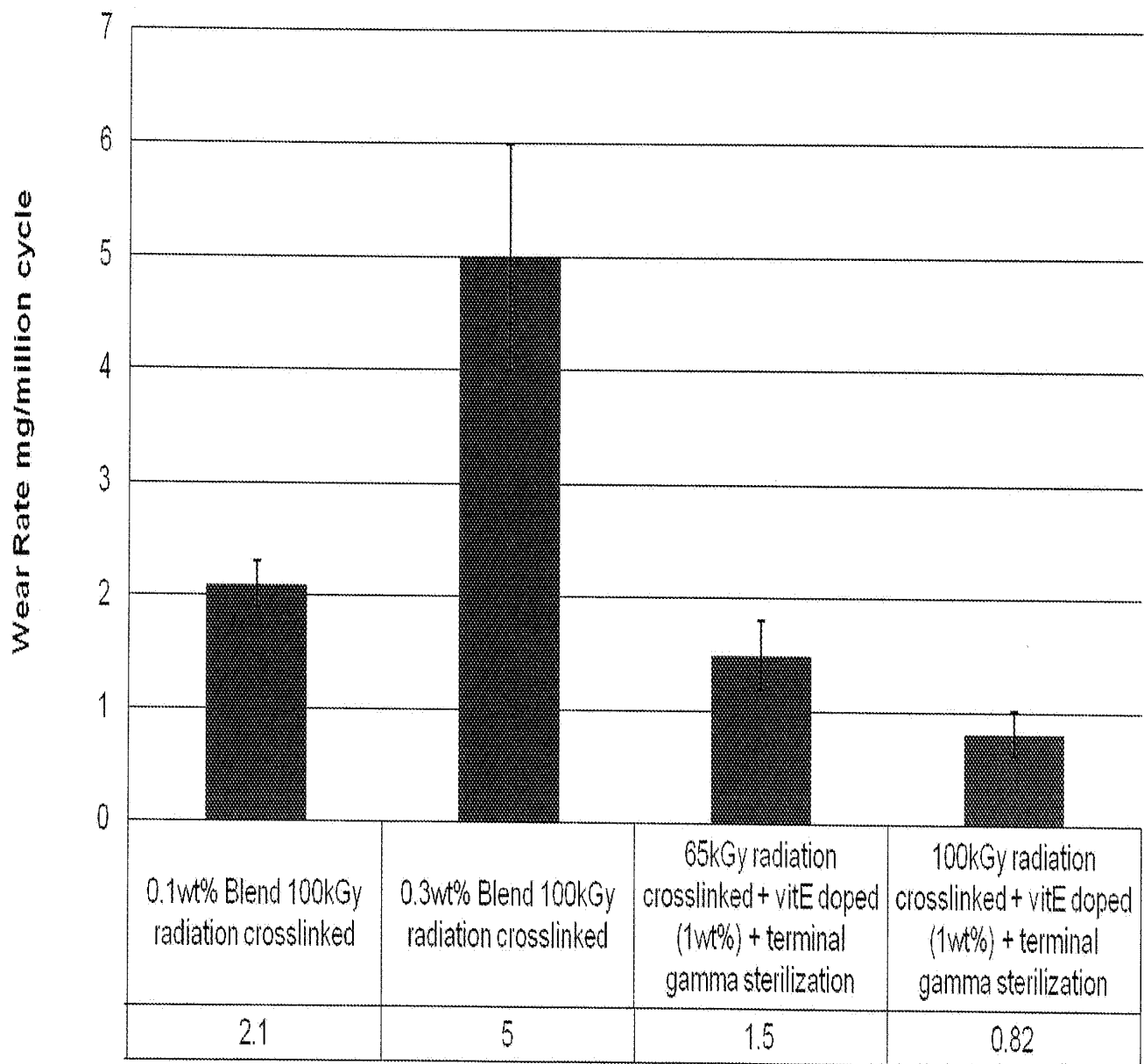
UHMWPE	Unaged fatigue resistance	Aged fatigue resistance	dx (mol/m <sup>3</sup> )
<b>Radiation sterilization (25 kGy)</b>	1.20	0.18	60
<b>Radiation (100 kGy)</b>	0.66	NT	175
<b>Radiation (100 kGy) → Melting</b>	0.54	0.51	175
<b>Radiation (100 kGy) → Dope Vit-E (1 wt%)</b>	0.77	0.72	175
<b>1wt% Blend → Radiation (100 kGy)</b>	~1.20	~1.20	73

Post-irradiation melting decreases fatigue strength.

Oxidation drastically reduces fatigue strength.

By using vitamin E doping after irradiation of consolidated UHMWPE, both problems are avoided.

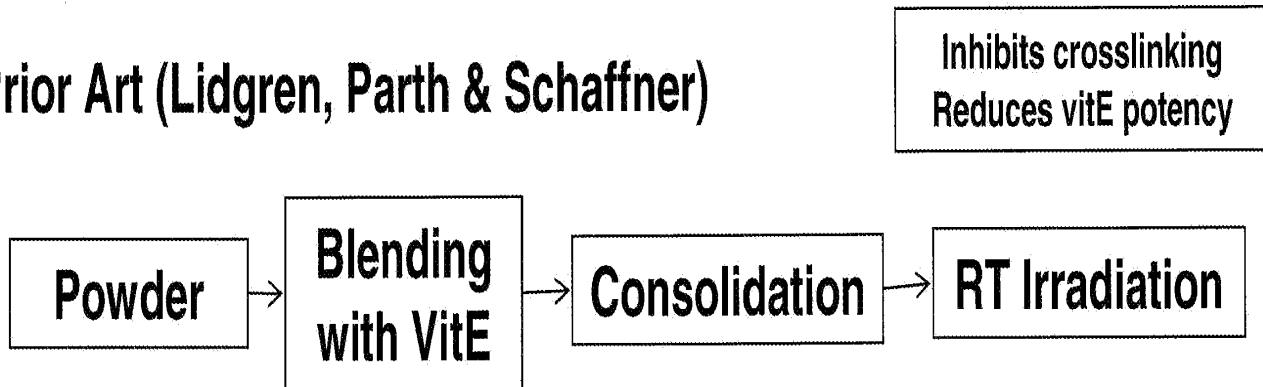
# From Examples 4 and 15 in the Specification



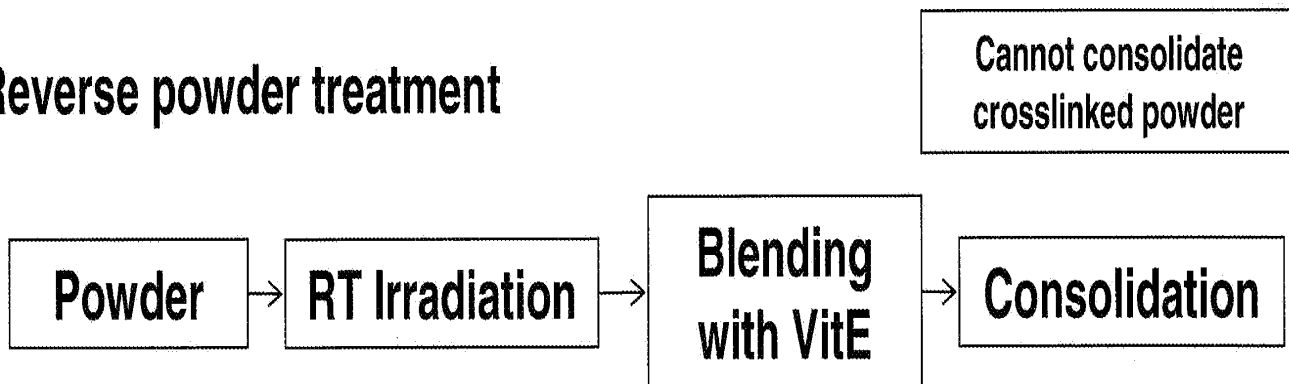
**All irradiation was at room temperature (RT)**

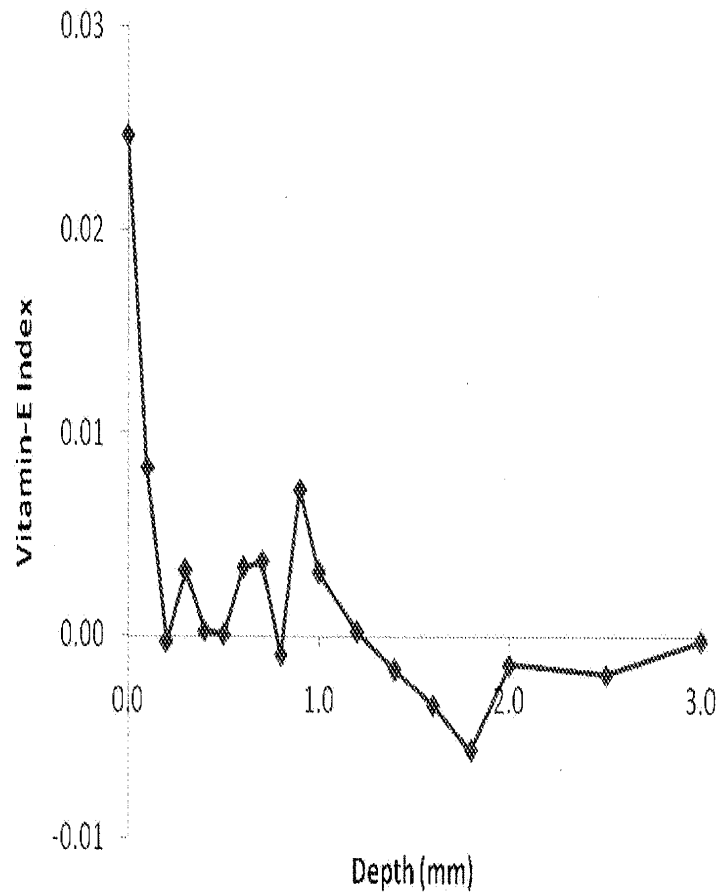
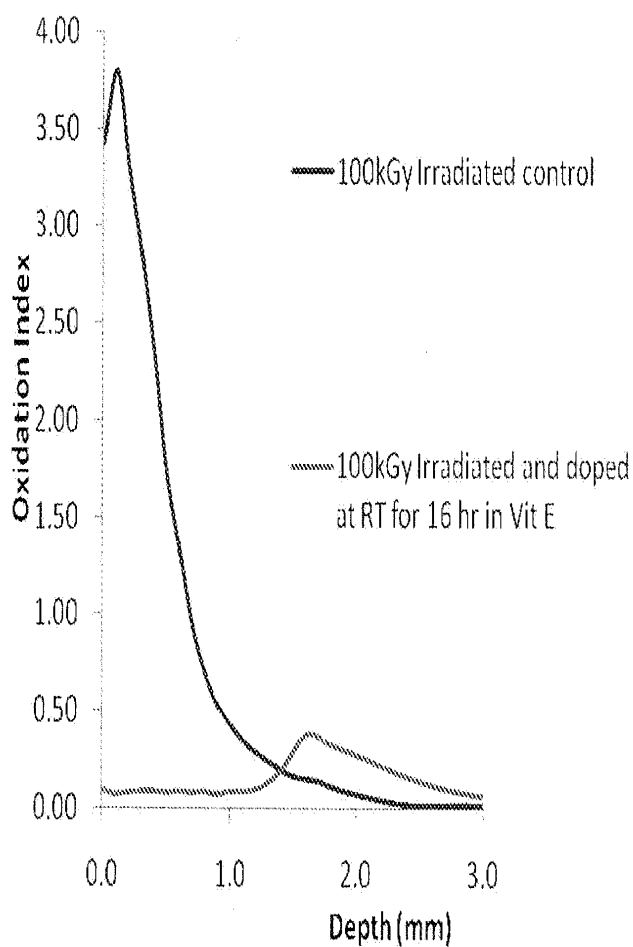
# Blends = VitE mixing before consolidation

Prior Art (Lidgren, Parth & Schaffner)



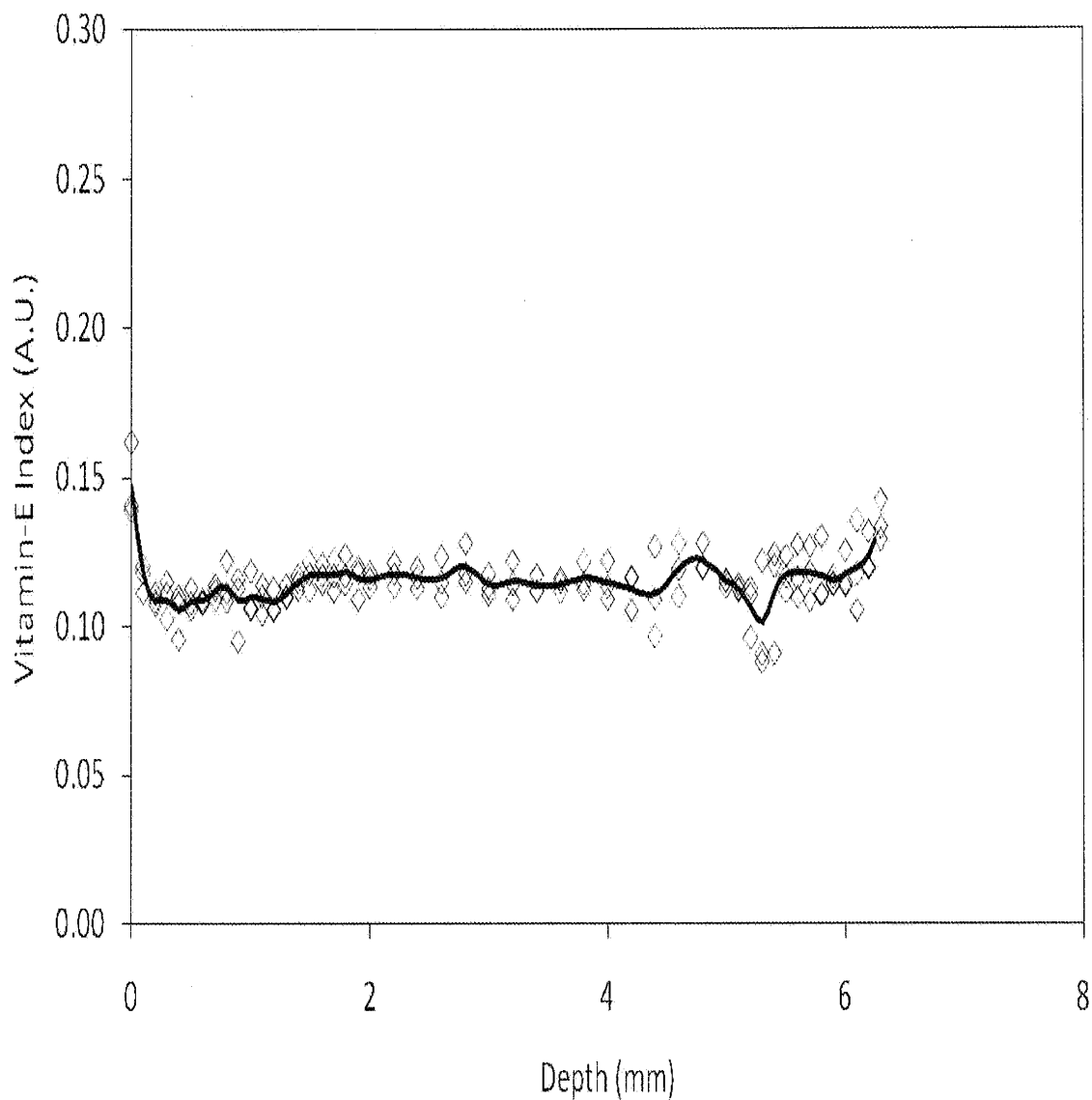
Reverse powder treatment





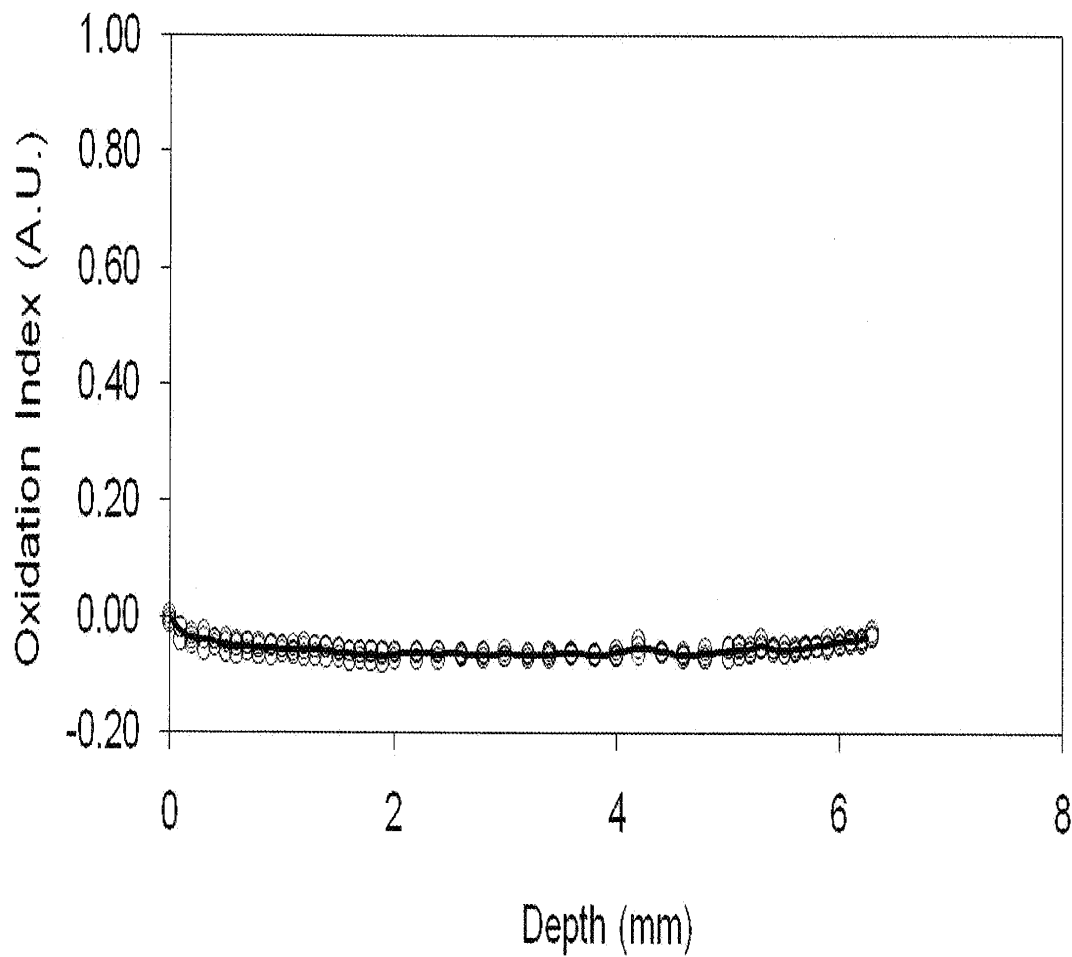
Samples: 100kGy irradiated UHMWPE.

Control (no vitamin E) and doped with vitamin E at room temperature by soaking and then aged in a pressure vessel at 5 atm of  $O_2$  gas at  $80^\circ C$  for 2 weeks. Vitamin E penetration was initially limited (graph on the right) after the doping step, and oxidation was eliminated near the subsurface region where there was vitamin E present, but oxidation started to occur beyond the depth where the vitamin E did not have a detectable presence (graph on left). Annealing to increase the uniformity of vitamin E presence avoids oxidation throughout the sample.



Vitamin E profile of irradiated and then doped and annealed sample (slide 23) that showed no oxidation after oven aging at 80° C. Vitamin E was distributed throughout the sample.





Irradiated and then doped and annealed sample after oven aging at 80° C showed no oxidation because vitamin-E was present throughout the thickness of the sample.